

## Summary of Product Characteristics

### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Alamycin Aerosol 3.2% w/v Cutaneous Spray, solution

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 140g aerosol can contains:

#### **Active Substance**

Oxytetracycline 3.2 % w/v  
(as oxytetracycline hydrochloride)

#### **Excipient**

Patent Blue V (E131) 0.3 % w/v

For a full list of excipients see section 6.1.

### 3 PHARMACEUTICAL FORM

Cutaneous Spray, solution  
A blue opaque solution

### 4 CLINICAL PARTICULARS

#### 4.1 Target Species

Cattle, sheep and pigs.

#### 4.2 Indications for use, specifying the target species

Alamycin Aerosol is indicated for topical use in the treatment of foot rot in sheep and topical infections caused by organisms sensitive to oxytetracycline in cattle, sheep and pigs.

#### 4.3 Contraindications

Do not use in animals with known hypersensitivity to the active substance.

#### 4.4 Special warnings for each target species

None.

#### 4.5 Special precautions for use

##### **Special precaution(s) for use in animals**

For external use only.

##### **Special precautions to be taken by the person administering the veterinary medicinal product to animals**

Keep away from eyes.

Use only in a well ventilated area.

Avoid inhalation and contact with skin.

Wash hands after use.

Wash any splashes immediately.

Do not spray on a naked flame or any incandescent material.

#### **4.6 Adverse reactions (frequency and seriousness)**

None known.

#### **4.7 Use during pregnancy, lactation or lay**

No adverse effects or foetal abnormalities have been observed following the administration of oxytetracycline aerosol during pregnancy and lactation.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

None known.

#### **4.9 Amounts to be administered and administration route**

##### Foot Rot

For the treatment of foot rot, clean the affected area prior to administration. Holding the can upright, spray at a distance of 6 - 8 inches away for a minimum of 5 seconds or until the area is covered.

Treated sheep should be allowed to stand on dry ground for one hour before returning to pasture.

##### Wounds :

Wounds should be cleaned prior to application.

#### **4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary**

Not applicable.

#### **4.11 Withdrawal Period(s)**

Meat : Zero days

Milk : Zero hours

### **5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic Group: Antibiotics for topical use; Oxytetracycline.  
ATCvet Code: QD06AA03.

#### **5.1 Pharmacodynamic properties**

Oxtetracycline is a bacteriostatic antibiotic that inhibits protein synthesis in susceptible bacteria. Inside the cell it binds irreversibly to receptors on the 30S subunit of the bacterial ribosome where it interferes with the binding of the aminoacyl-transfer RNA to the acceptor site on the messenger RNA ribosome complex. This effectively prevents the addition of amino acids to the elongating peptide chain, inhibiting protein synthesis.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Patent Blue V (E131)  
Magnesium chloride  
Povidone  
Propylene Glycol  
Ethanolamine  
Purified Water  
Isopropyl Alcohol  
Methyl Alcohol

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf-life**

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years

### **6.4 Special precautions for storage**

Pressurised container, protect from sunlight and do not expose to temperatures above 50°C.  
Store below 25°C.

### **6.5 Nature and composition of immediate packaging**

140g pressurised aluminium can with valves, caps and actuators.

### **6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials**

Do not incinerate or puncture the can even when empty.

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

## **7 MARKETING AUTHORISATION HOLDER**

Norbrook Laboratories (Ireland) Limited  
Rossmore Industrial Estate  
Monaghan  
Ireland

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA 22664/014/001

## **9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

30th September 2008

## **10 DATE OF REVISION OF THE TEXT**